



June 29, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Johnny Isakson
Senator
Committee on Finance
United States Senate

The Honorable Mark Warner
Senator
Committee on Finance
United States Senate

Submitted electronically to: chronic_care@finance.senate.gov

RE: Finance Committee Working Group Request for Input on Chronic Care Solutions

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

The Healthcare Compliance Packaging Council sincerely appreciates the opportunity to contribute to the Senate Finance Chronic Care Working Group's deliberations on solutions that will improve outcomes for Medicare patients. The HCPC is excited to learn about this bipartisan Working Group and we look forward to supporting your work to develop legislation that can benefit Medicare patients and others through our organization's focus on medication regimen adherence and patient safety.

Our organization, the Healthcare Compliance Packaging Council, (www.hcpconline.org) is a non-profit trade organization with members who are packaging machinery, materials and service providers with a focus on pharmaceutical safety and improving patient outcomes so you can see that our goals are aligned with those of your committee. We have been striving for improved patient adherence and outcomes since 1990, so we are thrilled that patient adherence issues are finally coming to the forefront amongst other healthcare and governmental organizations.

Packaging, a key component in adherence and safety

Much of the discussion on medication adherence has sought after solutions that start too late, i.e., after the pharmacy. It is the very packaging carrying the pharmaceuticals that should be a key component in promoting patient safety and improved medication adherence, yet our U.S. market continues with a practice of repackaging in the pharmacy, a practice most of the world has discarded as cumbersome, increasing risk of counterfeit introduction and fraught with potential for disastrous

errors on behalf of patients. The rest of the world has come to the realization that pharmacy repackaging has no place in modern, safe and efficient pharmacy.

The style of packaging we would suggest in place of current amber vials or plastic bottles is referred to as compliance-prompting packaging or adherence packaging. It quite often consists of a calendarized blister (think birth control pills) with days of the week, month and, if required, even AM/PM clearly labeled. These package forms are created before the pharmacy and travel through to the patient which eliminates many of the potential concerns introduced by current repackaging process. Imagine, the manufacturers' original package reaches the patient! This style of package then assists the Medicare patient or provider in adherence to the medication regimen as demonstrated through multiple studies in our attached whitepaper. This paper, *Improving Patient Adherence through Packaging*, outlines numerous studies conducted over more than 20 years that point to improved adherence and, in most instances, improved related health outcomes in direct correlation to providing more effective packaging to the patient. A demonstrable, easy to read indicator as to whether a dosage has or has not been taken assists in fulfilling two of the Chronic Care Working Group's goals, **effective use and coordination**, as well as allowing Medicare patients to **have a greater role in managing their health**. In addition to calendarized reminders, some of the adherence packaging developed by pharmaceutical manufacturers provide in-depth information on the patient's condition and provide methods of electronic engagement to further control their care.

Improving adherence, reducing counterfeits

In addition to accomplishing the primary goal of improving patient adherence and health outcomes, this style of packaging offers several other benefits that other adherence solutions cannot. The fact that this package passes through the pharmacy eliminates the introduction of counterfeit or gray market drugs since the original manufacturers' package stays intact. Recognize that the introduction of counterfeit or substandard drugs in the pharmacy represents insurance fraud. With CMS paying for almost 1/3 of prescription drugs in the US, this should be of particular interest.

Protecting product stability during the in-use stage

Also, this style of package, when created with proper barrier materials, also protects the individual doses of drug until utilized by the patient. The attached study, *HCPC Prescription Packaging In-Use Stability Research*, points to the adverse effects daily exposure to oxygen and moisture may have on non-coated, widely-used chronic care condition tablets of Simvastatin (for high cholesterol), Lisinopril (for high blood pressure/hypertension) and Metformin (for Type 2 Diabetes) when contained in multi-

dose containers, such as traditional amber pharmacy vials and plastic bottles, requiring repeated opening and closing, or low-barrier blister films that permit permeation. The attached study pinpoints increased physical degradation of these products in typical prescription cycles. This means that the quality of the drugs and quite possibly the efficacy of the drugs may be impacted by repeated environmental exposure.

Due to the information contained in the referenced whitepaper and study, the HCPC urges the committee to consider that the packaging of pharmaceuticals has a very real impact on the overall effectiveness of drugs by encouraging patients to be adherent, protecting the products from unscrupulous pharmacists and protecting the drug itself from the environment until consumed by the patient. A complete solution designed to improve chronic condition Medicare patient outcomes will include modernized patient adherence packaging as an integral component. The HCPC stands ready to bring forward ideas on adherence solutions that may not only improve outcomes, but also patient safety for those afflicted with chronic illnesses.

Sincerely,

A handwritten signature in black ink, reading "Walt Berghahn". The signature is fluid and cursive, with a long horizontal stroke at the end.

Walt Berghahn
Executive Director
Healthcare Compliance Packaging Council